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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,484	06/29/2005	Wei Zhang	2565/130	6518

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EXAMINER	
WIEST, PHILIP R	
ART UNIT	PAPER NUMBER
3761	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,484	ZHANG, WEI	
	Examiner	Art Unit	
	Phil Wiest	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/3/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 15, 20, 22, 24, 29, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Spickermann (EPO 911,044).

3. With respect to Claim 15, Spickermann discloses a method for the calculation of blood volume comprising a blood treatment apparatus 15, an arterial branch of the blood line 5 and a venous branch of the blood line 7. The blood circuit includes means for generating and measuring pulse waves that have a propagation rate and transfer time [0008]. Pulse waves are generated in the body by the cardiac system, and propagate into the extracorporeal system, where they are recorded by pressure sensor 46 [0033]. Therefore, Spickermann discloses the step of generating pulse waves in the extracorporeal system. Spickermann further discloses a computer unit which calculates the blood pressure from the pulse wave transit time [0012]. Once blood pressure and transit time are recorded from the sensors, blood volume can be calculated by the computer [0027 - 0029]. Regarding the generation of pulse waves in the extracorporeal

system, pulse waves created by the heart will transfer into the arterial line, where they are detected by the pressure sensor 46 [0033].

4. With respect to Claims 20 and 22, Spickermann discloses a method for the determination of a blood volume comprising the use of a computer that calculates blood pressure from the pulse wave transit time [0012]. Furthermore, regarding Claim 22, the computer is capable of calculating the relative blood volume using blood pressure and temporal change in the measured transit time [0027]. The "continuous, noninvasive measurement of blood pressure" allows volume calculations to be made at any set of times t and t_0 [0027]. Regarding the relative blood volume equation of Claim 22, Spickermann further discloses an equation for relating the blood volume in an extracorporeal system with pulse wave velocity and blood pressure. Spickermann utilizes the same variables as appear in the instant claims. Because the numerical data of the blood volume are neither disclosed nor claimed by Applicant, and because blood volume is a characteristic of the patient, it is the examiner's position that since the steps of the method are met by Spickermann, that the quantity of blood volume will be inherent regardless of the formula used.

5. With respect to Claim 24, Spickermann discloses an extracorporeal blood treatment device comprising a blood treatment apparatus 15, an arterial branch of the blood line 5 and a venous branch of the blood line 7. The blood circuit includes means for generating and measuring pulse waves that have a propagation rate and transfer time [0008]. Pulse waves are generated in the body by the cardiac system, and propagate into the extracorporeal system, where they are recorded by pressure sensor

46 [0033]. Therefore, Spickermann discloses the step of generating pulse waves in the extracorporeal system. Spickermann further discloses a computer unit which calculates the blood pressure from the pulse wave transit time [0012]. Once blood pressure and transit time are recorded from the sensors, blood volume can be calculated by the computer [0027 – 0029]. Regarding the generation of pulse waves in the extracorporeal system, pulse waves created by the heart will transfer into the arterial line, where they are detected by the pressure sensor 46 [0033].

6. With respect to Claims 29 and 31, Spickermann discloses that the blood circuit comprising a computer that calculates blood pressure from the pulse wave transit time [0012]. Furthermore, the computer is capable of calculating the relative blood volume using blood pressure and temporal change in the measured transit time [0027]. The "continuous, noninvasive measurement of blood pressure" allows volume calculations to be made at any set of times t and t_0 [0027]. Regarding the relative blood volume equation of Claim 31, Spickermann further discloses an equation for relating the blood volume in an extracorporeal system with pulse wave velocity and blood pressure. Spickermann utilizes the same variables as appear in the instant claims. Because the numerical data of the blood volume are neither disclosed nor claimed by Applicant, and because blood volume is a characteristic of the patient, it is the examiner's position that since the structural features of the device are met by Spickermann, that the quantity of blood volume will be inherent regardless of the formula used.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 15, 16, 17, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spickerman in view of Polaschegg (US 6,623,443)

9. With respect to Claim 16, Spickermann discloses the method of claim 15 (see above), but does not disclose that the pulse waves are generated by a blood pump arranged in the extracorporeal blood circuit. Polaschegg discloses a method and device for detecting stenosis in an extrecorporeal system wherein pressure pulses are created by a peristaltic pump and measured by sensors that may be built into the walls of the blood tubing (see Abstract). It would have been obvious to one skilled in the art at the time of invention to combine the extracorporeal monitoring method of Spickermann with the step of generating pulse waves using a pump of Polaschegg in order to allow the operator to change the rate at which pulse waves are generated. Doing so would allow pressure and volume to be calculated at any desired time interval based on the time between pulse waves.

10. With respect to Claim 17 Spickermann discloses a method for the determination of blood volume wherein a blood pump 6 and pressure sensor 46 are arranged in the extracorporeal blood circuit. Regarding Claim 16, it is well known in the art that the use

of a blood pump in a blood circuit will generate pulse waves. Furthermore, regarding Claim 19, Spickermann discloses that a pressure sensor 46 is arranged in the arterial branch of the blood line 5. See Figure 1.

11. With respect to Claim 25, Spickermann discloses the device of claim 24 (see above), but does not disclose that the pulse waves are generated by a blood pump arranged in the extracorporeal blood circuit. Polaschegg discloses a method and device for detecting stenosis in an extrecorporeal system wherein pressure pulses are created by a peristaltic pump and measured by sensors that may be built into the walls of the blood tubing (see Abstract). It would have been obvious to one skilled in the art at the time of invention to combine the extracorporeal monitoring device of Spickermann with the step of generating pulse waves using a pump of Polaschegg in order to allow the operator to change the rate at which pulse waves are generated. Doing so would allow pressure and volume to be calculated at any desired time interval based on the time between pulse waves.

12. With respect to Claim 26, Spickermann discloses that a blood pump 6 and pressure sensor 46 are arranged in the extracorporeal blood circuit.

13. Claims 18, 19, 21, 23, 27, 28, 30, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spickermann in view of Polaschegg, and further in view of Takahashi et al. (US 5,293,874).

14. With respect to Claims 18 and 19, Spickermann in view of Polaschegg discloses the method of Claims 15-17, and that the blood pump and pressure sensor are

arranged in the arterial branch of the blood line. Spickermann in view of Polaschegg, however, does not disclose that there two pressure sensors: one upstream of the blood treatment apparatus and one downstream of the blood treatment apparatus. Takahashi et al. disclose a method of measuring the transmission velocity of a pulse wave including sensors for sensing pulse waves at upstream and downstream sides of a blood flow (see Abstract). By sensing pulses at both ends of the extracorporeal blood circuit, pressure and volume measurements may be made at multiple points on the circuit. Therefore, it would have been obvious to one skilled in the art at the time of invention to combine the extracorporeal monitoring method of Spickermann with the pulse wave measurement at both the inflow and outflow ends of a blood line of Takahashi et al. in order to make system of measuring pulse waves at multiple positions. Placement of a pressure sensor in the venous line will allow for the measurement of pressure and volume of the blood after it passes the treatment apparatus and before it reenters the blood stream. Placement of a pressure sensor in the arterial line allows for measurement of pressure and volume of the blood leaving the body.

15. With respect to Claims 21 and 23, Spickermann discloses a method for the determination of a blood volume comprising the use of a computer that calculates blood pressure from the pulse wave transit time [0012]. Furthermore, regarding Claim 23, the computer is capable of calculating the relative blood volume using blood pressure and temporal change in the measured transit time [0027]. The "continuous, noninvasive measurement of blood pressure" allows volume calculations to be made at any set of

times t and t_0 [0027]. Regarding the relative blood volume equation of Claim 23, Spickermann further discloses an equation for relating the blood volume in an extracorporeal system with pulse wave velocity and blood pressure. Spickermann utilizes the same variables as appear in the instant claims. Because the numerical data of the blood volume are neither disclosed nor claimed by Applicant, and because blood volume is a characteristic of the patient, it is the examiner's position that since the steps of the method are met by Spickermann, that the quantity of blood volume will be inherent regardless of the formula used.

16. With respect to Claims 27 and 28, Spickermann in view of Polaschegg discloses the device of Claims 15-17, and that the blood pump and pressure sensor are arranged in the arterial branch of the blood line. Spickermann in view of Polaschegg, however, does not disclose that there two pressure sensors: one upstream of the blood treatment apparatus and one downstream of the blood treatment apparatus. Takahashi et al. disclose a device for measuring the transmission velocity of a pulse wave including sensors for sensing pulse waves at upstream and downstream sides of a blood flow (see Abstract). By sensing pulses at both ends of the extracorporeal blood circuit, pressure and volume measurements may be made at multiple points on the circuit. Therefore, it would have been obvious to one skilled in the art at the time of invention to combine the extracorporeal monitoring device of Spickermann with the pulse wave measurement at both the inflow and outflow ends of a blood line of Takahashi et al. in order to make system of measuring pulse waves at multiple positions. Placement of a pressure sensor in the venous line will allow for the measurement of pressure and

volume of the blood after it passes the treatment apparatus and before it reenters the blood stream. Placement of a pressure sensor in the arterial line allows for measurement of pressure and volume of the blood leaving the body.

17. With respect to Claims 30 and 32, Spickermann discloses that the blood circuit comprising a computer that calculates blood pressure from the pulse wave transit time [0012]. Furthermore, the computer is capable of calculating the relative blood volume using blood pressure and temporal change in the measured transit time [0027]. The "continuous, noninvasive measurement of blood pressure" allows volume calculations to be made at any set of times t and t_0 [0027]. Regarding the relative blood volume equation of Claim 32, Spickermann further discloses an equation for relating the blood volume in an extracorporeal system with pulse wave velocity and blood pressure. Spickermann utilizes the same variables as appear in the instant claims. Because the numerical data of the blood volume are neither disclosed nor claimed by Applicant, and because blood volume is a characteristic of the patient, it is the examiner's position that since the structural features of the device are met by Spickermann, that the quantity of blood volume will be inherent regardless of the formula used.

Response to Arguments

18. Regarding Claims 15 and 24, Applicant argues that Spickermann does not disclose the step of generating pulse waves in the extracorporeal system. However, although the waves are created within the body, they propagate through the blood line and into the extracorporeal system, where they are recorder by pressure sensor 46

(Column 6, Lines 32-35). Therefore, Spickerman does in fact disclose the generation of pulse waves in the extracorporeal system.

19. Applicant's arguments with respect to claims 16-23 and 25-32 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571) 272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PRW
3/29/07

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